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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,291	05/25/2001	Richard Oko	1669.0050001/JAG/EEF	1258

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EXAMINER
KAM, CHIH MIN

ART UNIT	PAPER NUMBER
1653	14

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/864,291	OKO ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-64 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-64 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:

I. Claims 1-7, 16-18, 22 (in part), 36, 46, 47, 49, 50, 52, 54, 55, 59, 63 and 64, drawn to an isolated polypeptide comprising (a) at least one of PPPGY and LPPAY, (or a sequence of PPXY) and (b) at least three domains comprising YGXPPXG, a pharmaceutical composition comprising the peptide, and a vaccine comprising the peptide, classified in class 530, subclass 350, and class 514, subclass 2.

II. Claims 8-15, 48, 53 and 60-62, drawn to an isolated polynucleotide encoding a polypeptide comprising (a) at least one of PPPGY and LPPAY, (or a sequence of PPXY) and (b) at least three domains comprising YGXPPXG, a gene comprising the polynucleotide, a vector comprising the gene, a host cell comprising the vector, and a method producing a polypeptide, classified in class 536, subclass 23.5, and class 435, subclasses 320.1 and 325.

III. Claims 19-21 and 22 (in part), drawn to an antibody, which specifically binds to the polypeptide comprising (a) at least one of PPPGY and LPPAY, and (b) at least three domains comprising YGXPPXG, and a pharmaceutical composition comprising the antibody, classified in class 530, subclass 387.1.

IV. Claim 22 (in part), drawn a pharmaceutical composition comprising a molecule of an agonist or antagonist of PT32, or an agonist or antagonist of c-Yes, classified in class 514, subclass 2.

V. Claim 23, drawn to a method for inducing oocyte activation, comprising contacting an oocyte with (a) at least one of the polypeptide of claim 1 and a c-Yes polypeptide, and (b) globozoospermic sperm or round spermatids, classified in class 530, subclass 350, and class 514, subclass 2.

VI. Claims 24, 44 and 56, drawn to a method for inducing oocyte activation, comprising contacting an oocyte with PT32, tyrosine kinase c-Yes, or SEQ ID NO:18, classified in class 530, subclass 350, and class 514, subclass 2.

VII. Claims 25-27 and 57, drawn to a method for enhancing fertility in a mammal, comprising expressing in a germ cell of the mammal a polypeptide comprising (a) at least one of PPPGY and LPPAY, and (b) at least three domains comprising YGXPPXG, or SEQ ID NO:18, classified in class 530, subclass 350, and class 514, subclass 2.

VIII. Claims 28 and 51, drawn to a method for treating globozoospermy, comprising expressing in spermatozoa or in round spermatids a polypeptide comprising (a) at least one of PPPGY and LPPAY, and (b) at least three domains comprising YGXPPXG, classified in class 530, subclass 350, and class 514, subclass 2.

IX. Claims 29 and 58, drawn to a method for identifying a modulator of oocyte activation, comprising contacting a test compound with an oocyte, and treating the oocyte with the polypeptide comprising (a) at least one of PPPGY and LPPAY, and (b) at least three domains comprising YGXPPXG, or SEQ ID NO:18, classified in class 530, subclass 350, and class 514, subclass 2.

X. Claim 30, drawn to a method for identifying a modulator of oocyte activation by detecting the modulation of the binding of the polypeptide comprising (a) at least one of

PPPGY and LPPAY, and (b) at least three domains comprising YGXPPXG to tyrosine c-Yes in the presence of a test compound, classified in class 530, subclass 350, and class 514, subclass 2.

XI. Claims 31 and 32, drawn to a method for inhibiting fertilization of a mammalian oocyte, comprising inhibiting the interaction of PT32 with tyrosine c-Yes, e.g., contacting the oocyte with antibody that specifically binds to PT32 or antibody that specifically binds to tyrosine c-Yes, classified in class 530, subclass 387.1.

XII. Claim 33, drawn to a method for inhibiting fertilization, comprising introducing into a mammal a polypeptide comprising (a) at least one of PPPGY and LPPAY, and (b) at least three domains comprising YGXPPXG, or an antigenic fragment thereof, classified in class 530, subclass 350, and class 514, subclass 2.

XIII. Claims 34 and 35, drawn to a fusion polypeptide comprising the polypeptide comprising (a) at least one of PPPGY and LPPAY and (b) at least three domains comprising YGXPPXG, covalently linked to a second polypeptide; or a vaccine comprising the fusion polypeptide, classified in class 435, subclass 69.7.

XIV. Claims 37 and 38, drawn to a method for diagnosing diminished fertility in a mammal, comprising measuring the level of the polypeptide comprising (a) at least one of PPPGY and LPPAY, and (b) at least three domains comprising YGXPPXG, or the level of tyrosine c-Yes in spermatozoa, classified in class 530, subclass 350, and class 514, subclass 2.

XV. Claims 39, 40 and 41, drawn to a method for diagnosing abnormal spermiogenesis in a mammal by comparing the pattern of the distribution of the polypeptide comprising

(a) at least one of PPPGY and LPPAY, and (b) at least three domains comprising YGXPPXG, or that of tyrosine c-Yes throughout mature spermatozoa with that throughout healthy, mature spermatozoa, classified in class 530, subclass 350, and class 514, subclass 2.

XVI. Claims 42, 43 and 45, drawn to a non-human transgenic mammal whose germ cells contain a disruption in the endogenous gene encoding PT32 or tyrosine c-Yes, classified in class 800, subclass 8.

Should Inventions I be elected, applicant is required to select amino acid sequence from SEQ ID NO:5 or SEQ ID NO:12. Each amino acid sequence, absent factual data to the contrary, is a distinct peptide. This is not species election.

Should Invention II be elected, applicant is required to select one nucleotide sequence from SEQ ID NO:4 or SEQ ID NO:11. Each nucleotide sequence, absent factual data to the contrary, is a distinct nucleotide. This is not species election.

Should Invention VI be elected, applicant is required to select PT32, tyrosine kinase c-Yes or SEQ ID NO:18 because these polypeptides which have different amino acid sequences, exhibit different chemical and physical properties, and have different functions, are patentably distinct. This is not species election.

Should Inventions XIV or XV be elected, applicant is required to select the polypeptide of claim 1 or tyrosine kinase c-Yes because these polypeptides which have different amino acid sequences, exhibit different chemical and physical properties, and have different functions, are patentably distinct. This is not species election.

2. The inventions are distinct, each from the other because of the following reasons:

The polypeptide of Invention I is related to nucleotide of Invention II because the polypeptide can be produced by the expression of nucleotide in the cell. The inventions are distinct because they are physically and functionally distinct chemical entities and the polypeptide can be made by another process such as solid phase peptide synthesis.

The method of Invention II and the product of I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide as claimed can be made by solid phase peptide synthesis.

The polypeptide of Invention I is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibody. The inventions are distinct because they are physically and functionally distinct chemical entities and because the protein can be used in another and materially different process from the use for production of the antibody such as to assay or purify the cognate receptor of the protein or in assays for the identification of agonists or antagonists of the receptor protein.

The polypeptide of Invention I is distinct from the products of Inventions IV and XVI because they are physically and functionally distinct chemical entities, and have different functions.

The polypeptide of Invention I is distinct from the fusion polypeptide of Invention XIII because they contain different amino acid sequences, and have different physical and chemical properties.

The product of Invention I and the methods of Invention V-X, XII, XIV and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Invention V-X, XII, XIV and XV are alternative processes of use of the polypeptide of Invention I.

The product of Invention I is distinct from the method of Invention XI because the product of Invention I can be neither made by nor used in the method of Invention XI.

The nucleotide of Invention II is distinct from the products of Invention III, IV, XIII and XVI because the products of these groups are physically and functionally distinct chemical entities, and the products of Inventions III, IV, XIII and XVI cannot be made by the product of Invention II.

The product of Invention II is distinct from the methods of Inventions V-XII, XIV and XV because the product of Invention II can be neither made by nor used in the methods of Invention V-XII, XIV and XV.

The product of Invention III and the method of Invention XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of Invention XI can be practiced with an antigenic peptide.

The products of Inventions III, IV, XIII and XVI are distinct from each other because they are physically and functionally distinct chemical entities and have different utilities.

The product of Invention III is distinct from the methods of Inventions II, V-X, XII, XIV and XV because the product of Invention III can be neither made by nor used in the methods of Inventions II, V-X, XII, XIV and XV.

The products of Inventions IV, XIII and XVI are distinct from the methods of Inventions II, V-XII, XIV and XV because the products of Inventions IV, XIII and XVI can be neither made by nor used in the methods of Inventions II, V-XII, XIV and XV.

The methods of Inventions II, V-XII, XIV and XV are distinct from each other because the method steps, the materials used and the outcomes are wholly different among Inventions II, V-XII, XIV and XV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications and recognized divergent subject matter, and because inventions I-XVI require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call was made to Nicholas Seay on September 5, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

Christopher S. F. Low
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September 5, 2002